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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,427	12/17/2003	Joel Morganroth	D5859-00021	8208

8933 7590 02/17/2009

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EXAMINER	
PORTER, JR, GARY A	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,427	MORGANROTH, JOEL	
	Examiner	Art Unit	
	GARY A. PORTER, JR	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-18 and 21-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 10-18 and 21-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 49 merely recites the same limitations as presented in parent Claim 47. Specifically requiring intervals for at least two heartbeats has already been recited.

2. Claim 53 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 53 merely recites the same limitations as presented in parent Claim 51. Specifically requiring intervals for at least two heartbeats has already been recited.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-18, 32-42, 44, 46 and 51-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The claims recite "means for" that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material or acts for the claimed functionalities.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-18, 32-42, 44, 46 and 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "means for" that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material or acts for the claimed functionalities.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 10, 21-31, 43, 45 and 47-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicants' claims are directed to a judicial exception of 35 U.S.C. 101. These claims

are directed to method claims that neither produce a physical transformation, nor positively recite a machine that implements the process. Regarding the physical transformation, data transformations aren't considered to render a process statutory; therefore, as an example in Claim 1, neither the steps of traversing collected demographic data nor the generation of a query are considered physically transforming. Regarding the recitation of a device or machine for implementing the process, these claims recite "a computer implemented method" in the preamble; however, this computer device is not positively recited in the main body of the claims. Mere recitation of "computer implemented" in the preamble is not sufficient to tie the claimed process to another statutory category; therefore, the method is considered nonstatutory. These claims can be amended to recite a machine that implements these steps in the body of the claim in order to be considered statutory.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 6-8, 10, 11, 12, 16-8 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Morganroth et al. (*How to Obtain and Analyze Electrocardiograms in Clinical Trials…*)

10. Regarding Claims 1, 2, 11, 12, 43 and 44, Morganroth teaches receiving digital demographic and protocol data for a clinical study (page 431-432), verifying the

accuracy of the data by comparing it to a sponsor's protocol/database and generating a query after the comparison to ensure a rigorously controlled archive of source documents and quality assured database management (page 432, second paragraph).

11. In regards to Claims 1 and 11, The Examiner also notes that Applicant has stated in the background of the invention that the process receiving demographic data and cross-checking of demographic data in a clinical study has been established as a well known manual process (Paragraph [0003-0011]). Applicant also claims (in Claim 1) that digital demographic data is received, "traversed" with a base set of data, and corrected by submission of a query upon finding an error or discrepancy. In other words, this process only differs from the manual process disclosed by Applicant by being "computer implemented", as stated in the preamble, and also by formatting the demographic data as a digital data set as opposed to a hard copy. However, the Examiner notes that it has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

12. Regarding Claims 6 and 16, Morganroth teaches receiving ECG data of a clinical study, analyzing the ECG data at a core laboratory that comprises cardiologists, and reanalyzing the data when safety issues arise (Page 427).

13. Further regarding Claims 6 and 16, The Examiner also notes that Applicant has stated in the background of the invention that the process of Claim 6 is a well known manual method (Paragraph [0003-0011]). The claimed process only differs from the manual process disclosed by Applicant by being "computer implemented", as stated in

the preamble. However, the Examiner notes that it has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

14. In regards to Claim 7, Morganroth teaches that the core laboratory measures and interprets the ECG data (page 427). Furthermore, Morganroth teaches that one technician analyzes an ECG using a computer process that submits the data to a database for further review (page 428; col. 2). Lastly, Morganroth teaches that the data is analyzed, and since the data was stored in a database, the annotated ECG images are inherently displayed to the examining technician (page 428, col. 2).

15. Regarding Claim 8, Morganroth teaches establishing quality protocols (page 431, col. 2), and regulating (Examiner notes the regulation can be done electronically) received digital ECG data (page 431-432) based on the defined protocols (page 432, col. 1).

16. In regards to Claim 10, Morganroth teaches receiving ECG data from a clinical study (page 427, col. 2), receiving interval duration data (page 429) and providing the ECG data and digital intervention data to a regulatory agency (i.e. the FDA or a core laboratory (page 431-432)).

17. Regarding Claim 17, Morganroth teaches a computer where analytical data is stored and then reviewed from. In this manner, there is inherently a monitor available to allow a physician to view the data entered into the computer (page 428, col. 2- page 429, col. 1).

18. In regards to Claim 18, Morganroth teaches a telemetry transmission system for receiving digital parameter data and a means for identifying said at least one ECG based on digital evaluation data (page 431, col. 2-page 432, col. 1).

19. With regards to Claims 45 and 46, Morganroth teaches reanalyzing an ECG when a safety issue is raised (page 427).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 3-5 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morganroth et al. (*How to Obtain and Analyze Electrocardiograms in Clinical Trials…*) in view of Rabin (US 6,603,464).

22. Regarding Claims 3, 4, 13 and 14, Morganroth discloses all of the claimed invention except for notifying an internal contact of a problem. However, Rabin teaches a medical data management system that is capable of resolving an automatic query internally (i.e., an auditory alert to an internal contact) or externally (i.e., phone external contacts) (col. 8, lines 60-63). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Morganroth reference to include internal query resolution, as taught and suggested by Rabin, for the purpose of promptly notifying medical personnel of a problem in order to expediently fix the issue.

23. In regards to Claims 5 and 15, Morganroth discloses all of the claimed invention except for the specific criteria for identifying problems of the demographic data. However, Rabin teaches a medical data management system that includes the step of identifying missing data from said collected demographic data (i.e. a potential drug interaction that was omitted) (col. 8, lines 56-60). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Morganroth reference to include identifying missing data from the collected demographic data, as taught and suggested by Rabin, for the purpose of correcting any data critical to the study.

24. Claims 21-42 and 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morganroth et al. (*How to Obtain and Analyze Electrocardiograms in Clinical Trials…*) in view of Badilini (US 2002/0172404).

25. Regarding Claims 21, 25, 28, 32, 36, 39, 50 and 54, Morganroth teaches analyzing a base ECG and then storing the individual interval markers in a database without altering the base ECG data. Therefore, the annotation data is recorded apart from the ECG image. Furthermore, since the ECG is electronically stored in a computer database, it is inherent that the ECG can be viewed on a computer monitor (page 428, col. 2). Morganroth does not teach explicitly displaying the annotated ECG tracing image on a display. However, Badilini teaches an ECG processing system and method wherein ECG data is received by scanning an ECG plot 10 with scanner 64, or directly

from an ECG machine, wherein an ECG plot is inherently produced from at least one ECG lead and contains a plurality of a patient's heartbeats (par. 0038, 0062 and figure 4). An ECG tracing image with a plurality of heartbeats is then displayed on a display of a user terminal (par. 0038). The user then identifies a plurality of interval points for a plurality of intervals on the displayed ECG tracing image to be measured using a moveable caliper (i.e., mouse pointer) (par. 0046-0058). As seen in figure 9, a plurality of time durations of the identified intervals are determined, recorded and displayed to a party. Furthermore, an annotated ECG tracing image showing the markings made by the user is saved (par. 0060). Although Badilini does not teach a system that records annotation data apart from the ECG image, Badilini does teach that it is known to display annotated ECG images on a display for further analyzing. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Morganroth reference to include displaying annotated ECG data on a screen, as taught and suggested by Badilini, for the purpose of allowing further scrutiny of the ECG of the clinical study.

26. Additionally, regarding Claims 21 and 32, Applicant discloses in the background of the invention that the method of Claim 21 is a well known manual process. The Examiner notes that it has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

27. In regards to Claims 22, 26, 33 and 37, Morganroth teaches using a computerized puck to mark points of interest on an ECG and the submitting digital information to a database that corresponds to the points of interest of the ECG (page 428, col. 2).

28. Regarding Claims 23 and 34, Morganroth discloses displaying an ECG with at least 3 heartbeats, as can be seen in Figure. 1.

29. With regards to Claims 24, 27, 35, 38, 48 and 52, Morganroth teaches that the intervals correspond to RR, PR, QRS and QT intervals (page 428).

30. In regards to Claims 29 and 40, Morganroth teaches analyzing an ECG, storing markers indicating areas of interest of an ECG in a database, and then analyzing the data. The physician will inherently have a display to see the data since the data is stored on a computer and must be connected to a monitor in order to view the results. (page 428-429).

31. Regarding Claims 30 and 41, Morganroth teaches that the digital data is provided to an evaluating physician (page 427 and 432).

32. With regards to Claims 31 and 42, Morganroth teaches generating a report for an annotated ECG image and providing said report to the specified sponsor (page 432) (page 432).

33. In regards to Claims 47, 49, 51 and 53, Morganroth teaches receiving identification of interval points from at least two heartbeats since comparison's between successive intervals are completed, which requires more than one heart beat. An interval requires at least two beats. (Page 428-429).

Allowable Subject Matter

34. Claims previously indicated allowable have now been rejected in light of newly found art. See rejection above.

Response to Arguments

35. Applicant's arguments with respect to claims 1-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is

(571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766